UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

RHODE ISLAND HOSPITAL,

v.

Plaintiff

C.A. No. 06-05T

MICHAEL O. LEAVITT, et al.

Defendants.

MEMORANDUM OF DECISION

ERNEST C. TORRES, Senior District Court Judge

Introduction

Rhode Island Hospital ("RIH") has appealed from a decision by the Secretary of Health and Human Services ("the Secretary") which excluded time spent on research in counting how many full-time equivalent residents ("FTEs") RIH had during 1996, thereby, reducing the Indirect Medical Education ("IME") adjustment due RIH as compensation for the additional costs it incurred in providing graduate medical education ("GME") to residents, interns and fellows (collectively "residents"). More specifically, RIH challenges the Secretary's determination that, under the version of 42 C.F.R. § 412.105(g) in effect during 1996 ("the Regulation"), only time spent on direct patient care could be counted in calculating the number of FTEs.

The parties have filed cross-motions for summary judgment and,

because I find that the Secretary's determination is inconsistent with both the Regulation's plain language and Congress's purpose in providing for IME payments to teaching hospitals, RIH's motion for summary judgment is granted and the Secretary's motion for summary judgment is denied.

Background

The Prospective Payment System ("PPS")

"Acute care" hospitals that have entered into provider agreements with the Secretary are eligible to receive payments for medical services provided to Medicare beneficiaries, subject to the conditions set forth in the applicable Medicare statutes and regulations. 42 U.S.C. §§ 1395x(u), 1395cc.

Before 1983, hospitals were paid the "reasonable cost" of providing those services. 42 U.S.C. § 1395x(v). In 1983, in an effort to give hospitals an incentive to render services in the most cost-efficient manner possible, Congress adopted the Prospective Payment System ("PPS"). Under PPS, hospitals are reimbursed, at a predetermined rate (the "reimbursement rate"), for the cost of providing inpatient services. 42 U.S.C. § 1395ww(d). The reimbursement rate is based on the patient's "Diagnosis-Related Group" ("DRG") which is determined by the condition for which the patient was treated. 42 C.F.R. § 412.60. Consequently, if a hospital's costs for providing a particular service are less than

the reimbursement rate, the hospital may realize a profit, but if the hospital's costs exceed the reimbursement rate, the hospital must absorb a loss. See Riverside Methodist Hosp. v. Thompson, 2003 WL 22658129, at *2 (S.D. Ohio July 31, 2003).

However, PPS was not made applicable to all hospitals or even to all units of a hospital. It applied only to "subsection (d) hospitals," which consisted of acute-care hospitals, and specifically excluded, inter alia, psychiatric hospitals and rehabilitation hospitals, as well as psychiatric or rehabilitation units that were distinct parts of a subsection (d) hospital. 42 U.S.C. § 1395ww(d)(1)(B). The reason for excluding those hospitals and units was that they continued to be reimbursed on a reasonable cost basis. See 48 Fed. Reg. 39,752, 39,778 (Sept. 1, 1983).

<u>Direct Medical Education (DME) and Indirect Medical Education (IME)</u> <u>Adjustments</u>

Since Congress determined that teaching hospitals incur costs in training residents that are not taken into account by PPS's predetermined rates, Congress provided for additional payments to such hospitals in order to reimburse them for those costs. See H.R. Rep. No. 98-25(I) at 140-41 (1983), as reprinted in 1983 U.S.C.C.A.N. 219, 359-60; S. Rep. No. 98-23, at 52-53 (1983), as reprinted in 1983 U.S.C.C.A.N. 143, 192.

The additional payments have two components. The <u>direct</u> costs

of providing medical education, which consist of readily ascertainable expenses like resident salaries, are reimbursed by means of a Direct Medical Education ("DME") adjustment which is sometimes referred to as a "Direct graduate medical education payment" or GME adjustment. See 42 U.S.C. § 1395ww(h); University Medical Center Corp. v. Leavitt, 2007 WL 891195 at *4 (D. Ariz. Mar. 21, 2007); Riverside Methodist, 2003 WL 22658129 at *2 n.4; 42 C.F.R. § 413.86 (1996). See also H.R. Rep. No. 98-25(I) at 140 (1983), as reprinted in 1983 U.S.C.C.A.N. 219, 359; 42 C.F.R. § 413.75 (2007). Indirect costs that are not so easily identified or quantified are reimbursed by means of an "Indirect Medical Education" ("IME") adjustment. 42 U.S.C. § 1395ww(d) (5) (B).

Congress perceived the indirect costs as including "the additional tests and procedures ordered by residents as well as the extra demands placed on other staff as they participate in the education process. . . ." S. Rep. No. 98-23, at 52-53 (1983) as reprinted in 1983 U.S.C.C.A.N. 143, 192, and it adopted "teaching intensity" as the basis for approximating those costs. More specifically, Congress approved a formula under which the IME adjustment is calculated by multiplying a hospital's PPS payment by its "IME factor." The IME factor is arrived at by means of a formula, most components of which are numbers fixed by Congress, and a number for "teaching intensity," which is expressed as the ratio of the hospital's number of FTEs to the number of beds in the

hospital. See H.R. Rep. No. 98-25(I) at 140-41, as reprinted in 1983 U.S.C.C.A.N. 219, 359; 48 Fed. Reg. 39,752, 39,778 (Sept. 1, 1983); 51 Fed. Reg. 16,772-01, 16,775 (May 6, 1986) ("these incremental costs have been statistically estimated as a function of teaching intensity, and a proxy measure (the hospital's ratio of the number of interns and residents to the number of beds) has been used to measure teaching intensity."). Accordingly, under the formula, a hospital's IME adjustment is directly proportional to the number of its FTEs.

Calculating the Number of FTEs

During 1996 the method for calculating FTEs was prescribed by what, then, was 42 C.F.R. § 412.105(g) (1996) ("the Regulation"). The Regulation required that, in order to be included in the FTE calculation, a resident must have been: (1) "enrolled in an approved teaching program" and (2) "assigned to . . . [t]he portion of the hospital subject to the prospective payment system." 42 C.F.R. § 412.105(g)(i), (ii)(A) (1996). The Regulation further provided that FTE status was "based on the total time necessary to fill a residency slot" and that, in the case of a resident who

The statutory formula for calculating the indirect teaching adjustment factor ("IME factor") is c * (((l + r) ^ n) - l) where "r" is the ratio of FTE resident to beds or "teaching intensity", n= .405 (a statutorily established factor representing the effect of teaching activity on the hospital's indirect costs), and "c" is an adjustment factor established annually by Congress. 42 U.S.C. § 1395ww(d)(5)(B)(ii).

spent part of his time working in a hospital or hospital unit not subject to PPS, that resident "would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital [subject to PPS], compared to the total time necessary to fill a full-time internship or residency slot." 42 C.F.R. § 412.105(q) (iii) (1996).

In 2001, subsection (g) became what is now subsection (f) of 42 C.F.R. § 412.105 and it was amended to include what the Secretary refers to as a "clarification" that, in calculating FTEs, "[t]he time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. § 412.105(f)(1)(iii)(B) (2001). See University Medical Center Corp., 2007 WL 891195 at *5.

RIH's FTEs

RIH is a non-profit hospital that participates in Medicare and operates graduate medical education programs for residents that require the residents to participate in "scholarly activities" such as research. The programs are accredited by the Accreditation Council for Graduate Medical Education ("ACGME"); and, therefore, are recognized as "approved" programs for Medicare purposes. 42 C.F.R. § 412.105(q)(1)(i) (1996); 42 C.F.R. § 415.152 (1996).

In seeking its IME adjustment for 1996, RIH included in its FTE calculation time spent by residents in the research component

of its approved residency programs. However, Blue Cross & Blue Shield of Rhode Island, RIH's fiscal intermediary, excluded that time from the FTE calculation thereby reducing the hospital's IME payment by approximately \$1,000,000. RIH appealed to the Provider Reimbursement Review Board ("PRRB") which found that research time was properly includable. However, the Administrator of the Center for Medicare and Medicaid Services, acting as the Secretary's delegate, interpreted the Regulation as excluding research time from the FTE calculation because it does not constitute direct patient care and, therefore, the Administrator reversed the PRRB's decision. 42 C.F.R. § 405.1875. Since the Administrator's decision is deemed the final decision of the Secretary, it is subject to judicial review under § 139500(f)(1). 42 U.S.C. § 139500(f)(1); Riverside, 2003 WL 226581259 at *3.

RIH has appealed, claiming that the Secretary's interpretation of the Regulation is erroneous; or, alternatively, that if the Secretary's interpretation is upheld, the Regulation is invalid.

Standard of Review

Under 42 U.S.C. § 139500(f), the Secretary's decision is subject to judicial review in accordance with section 706 of the Administrative Procedure Act. Section 706 provides that a reviewing court may reverse the Secretary's decision only if it is "'arbitrary, capricious, an abuse of discretion, or otherwise not

in accordance with the law' or 'unsupported by substantial evidence.'" Visiting Nurse Ass'n Gregoria Auffant, Inc. v. Thompson, 447 F.3d 68, 72 (1st Cir. 2006) (citing 5 U.S.C. § 706(2)).

In deciding whether an agency's interpretation of its own regulation should be upheld, a reviewing court, first, must look to the regulation as written. If the regulation is clear on its face, it cannot be altered by an interpretation that is inconsistent with its plain language. South Shore Hosp., Inc. v. Thompson, 308 F.3d 91, 97, 98 (1st Cir. 2002) (An agency's interpretation of its regulation is not entitled to deference when "plainly erroneous or inconsistent with its language." (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512, 114 S.Ct. 2381, 2386-87, 129 L. E. 2d 405 (1994))). On the other hand, if the regulation is susceptible to different interpretations, the agency's interpretation is entitled to substantial deference, provided that it is reasonable and not inconsistent with indications of the Secretary's intent at the time the regulation was adopted. Thomas Jefferson Univ. v. Shalala, 512 U.S. at 512 (courts "must defer to the Secretary's interpretation unless an 'alternative reading is compelled by the regulation's plain language or by other indication of the Secretary's intent at the time of the regulation's promulgation." (quoting Gardebring v. Jenkins, 485 U.S. 415, 430, 108 S.Ct. 1306, 1314, 99 L. E. 2d 515 (1988))); South Shore Hosp., Inc., 308 F.3d

at 98. As the First Circuit stated in South Shore:

Despite the fact that Medicare rules fall squarely within the Secretary's domain, deference is due to the Secretary's interpretation of a particular regulation only when the language of a regulation either (1) compels that interpretation or (2) admits of differing interpretations, and the Secretary chooses reasonably among them.

South Shore Hosp., Inc., 308 F.3d at 98 (emphasis added); see Gonzales v. Oregon, 546 U.S. 243, 255, 126 S.Ct. 904, 914-15, 163 L. E. 2d 748 (2006) ("An administrative rule may receive substantial deference if it interprets the issuing agency's own ambiguous regulation.") (emphasis added).

In any event, the deference ordinarily accorded an agency's interpretation of an ambiguous regulation, however reasonable that interpretation might be, should not be construed as sanctioning the promulgation of vaguely or imprecisely worded regulations that confer <u>carte blanche</u> on the agency to make up the law as it goes along and, thereby, allow the agency to circumvent the rulemaking process. <u>See Thomas Jefferson Univ.</u>, 512 U.S. at 525 (Thomas, J., dissenting) ("It is perfectly understandable, of course, for an agency to issue vague regulations, because to do so maximizes agency power and allows the agency greater latitude to make law through adjudication rather than through the more cumbersome rulemaking process. Nonetheless, agency rules should be clear and definite so that affected parties will have adequate notice concerning the agency's understanding of the law.").

In determining whether an agency's interpretation of its regulations is reasonable, the Court must view that interpretation in light of "the language of the regulations and the policies they were meant to implement." McCuin v. Sec'y of HHS, 817 F.2d 161, 168 (1st Cir. 1987). The Court, also, "must consider whether the regulation so interpreted is consistent with the statute under which it is promulgated." Chesire Hosp. v. New Hampshire-Vermont Hosp. Serv., Inc., 689 F.2d 1112, 1118 (1st Cir. 1982).

<u>Analysis</u>

I. The 2001 Amendment

As a preliminary matter, it should be noted that the 2001 amendment to the Regulation which excludes research time from the FTE calculation has no bearing on this case. If, as the Secretary contends, the amendment merely "clarifies" what the Regulation already said, it adds nothing to the analysis. On the other hand, if the amendment imposes a new requirement that resident time must be spent on direct patient care in order to be counted in the FTE calculation, it cannot be applied retroactively.

II. The Regulation's Plain Language

The relevant portion of the Regulation provided:

- (1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent residents for the purpose of determining the indirect medical education adjustment is determined as follows:
- (i) The resident must be enrolled in an approved teaching program. An approved teaching program is one that meets

one of the following requirements:

- (A) Is approved by one of the national organizations listed in § 415.200(a) of this chapter.
- (B) May count towards certification of the participant in a specialty or subspecialty listed in the Directory of Residency Training Programs published by the American Medical Association.
- (C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine. . . .
- (ii) In order to be counted, the resident must be assigned to one of the following areas:
- (A The portion of the hospital subject to the prospective payment system.
- (B) the outpatient department of the hospital. . . . (iii) Full-time equivalent status is based on the total time necessary to fill a residency slot. No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of the time worked in any of the areas of the hospital listed in paragraph (g)(1)(ii) of this section, to the total time worked by the resident. part-time resident or one working in an area of the paragraph hospital other than those listed under (g) (1) (ii) of this section (such as a freestanding family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (g)(1)(ii) of this section, compared to the total time necessary to fill a full-time internship or residency slot.

42 C.F.R. § 412.105(g) (1996).

According to the plain language of sub-paragraphs (i) and (ii) there are only two applicable requirements that must be satisfied in order for a resident to be included in calculating the number of FTEs: (1) "[t]he resident must be enrolled in an approved teaching program" and, (2) "the resident must be assigned to . . . [t]he portion of the hospital subject to the prospective payment system."

There is nothing in subparagraphs (i) or (ii) that requires a resident to provide direct patient care in order to be counted.

Nor is there anything in subparagraph (iii) that excludes time spent on research from the FTE calculation or that requires time to be spent on direct patient care in order to be credited. On the contrary, subparagraph (iii) simply compares the time during which a resident is "assigned to . . . the portion of the hospital subject to [PPS]" to "the total time necessary to fill a residency slot."

Accordingly, by interpreting the Regulation as requiring that resident time be spent rendering direct patient care and, thereby, excluding time spent on research, the Secretary, in effect, has engrafted an additional requirement that is not contained in the Regulation as written.

The Secretary argues that, because the prospective payment system reimburses hospitals only for services directly related to the diagnosis or treatment of a particular patient, a direct patient care requirement is implicit in the requirement of subparagraph (ii), that, in order to be counted a resident must be "assigned to . . . [t]he portion of the hospital subject to the prospective payment system" and in the provision in subparagraph (iii) that only the "proportion of time assigned to an area of the hospital listed in paragraph (g) (1) (ii)" is credited toward FTE status. That argument is inconsistent with the plain meaning of

the Regulation.

Subparagraph (ii) provides that, in order for a resident's time to be counted in making the FTE calculation, what must be "subject to" or covered by PPS is not the specific activity engaged in by the resident; but, rather, "[t]he portion of the hospital" to which the resident is "assigned." The requirement that "the" portion of the hospital to which a resident is assigned must be "subject to" PPS merely distinguishes between those units of a hospital, such as psychiatric or rehabilitation units, that were statutorily excluded from PPS and "the" remaining portion of an acute care hospital. As the Ninth Circuit stated in interpreting similar Medicare regulations dealing with the add-on payment for disproportionate share hospitals, "[t]he regulations begin with the presumption that an area is covered by PPS, unless specifically exempted." Alhambra Hosp. v. Thompson, 259 F.3d 1071, 1074 (9th Indeed, the fact that the "subject to [PPS]" Cir. 2001). requirement was intended only to eliminate duplicative payments for costs incurred by specifically excluded portions of a hospital that continued to be reimbursed on a reasonable cost basis is made clear by the Secretary's own explanation of the Regulation when it was promulgated:

The teaching [IME] adjustment does not apply to any hospital not paid under the prospective payment system, such as those hospitals or distinct part psychiatric and rehabilitation units that are paid on a reasonable cost basis, since the payments to those facilities already include the indirect cost of medical education.

Therefore, the number of beds in an excluded psychiatric and rehabilitation unit, as well as interns and residents assigned those units, may not be included in calculating the ratio of interns and residents to beds.

48 Fed. Reg. 39,752-01, 39,778 (Sept. 1, 1983).²

Moreover, the Regulation states only that a resident must be "assigned" to the portion of the hospital subject to PPS. The regulation does not specify the activities in which a resident must engage while so assigned in order to be eligible for FTE credit.

The Secretary's interpretation also is at variance with the requirement in subparagraph (i) that a resident must be enrolled in an approved teaching program. As already noted, RIH's approved teaching program requires residents to engage in research activities; and, therefore, it would be incongruous to exclude the time spent on such activities from the FTE calculation.

In short, reading into the requirement that a resident must be "assigned" to "the portion of the hospital subject to the prospective payment system" a further requirement that, while so assigned, the resident must perform direct patient care is inconsistent with both the plain language of the Regulation and its stated purpose.

²Moreover, 42 C.F.R. § 412.105(b) (1996) provides that all beds in a hospital should be counted in determining the ratio of FTEs to beds unless they are "in excluded distinct part hospital units." Consequently, it would be incongruous not to read subparagraph (iii) as also including in the FTE calculation all time spent by a resident in filling a residency slot.

III. The Reasonableness of the Secretary's Interpretation

For many of the reasons already stated, even if the Secretary's interpretation is not viewed as contrary to the Regulation's plain language, the interpretation is not reasonable.

As previously stated, the purpose of the IME adjustment is to reimburse teaching hospitals for what Congress perceived to be the additional indirect costs incurred in training residents, including "the extra demands placed on other staff as they participate in the education process." H.R. Rep. No. 98-25(I) at 140 (1983), as reprinted in 1983 U.S.C.C.A.N. 219, 359; S. Rep. No. 98-23, at 52-53 (1983) as reprinted in 1983 U.S.C.C.A.N. 143, 192. The significance that Congress attached to the demands of the "education process" as part of the additional costs contemplated by the IME adjustment is highlighted by the adoption of "teaching intensity" as an important factor in making the calculation. light of the focus on "teaching intensity" as a measure of the additional costs for which the IME adjustment was intended to compensate; and, given the fact that the ratio of FTEs to beds serves as a "proxy" for teaching intensity, it is unreasonable to construe the Regulation as excluding from the FTE count time that residents spend on research that is required by the hospital's "approved teaching program" and that adds to the demands that the education process imposes on the hospital. Put another way, crediting only resident time spent on "direct patient care" ignores the fact that research, also, is part of the teaching process and, that it also contributes to the increased costs incurred by teaching hospitals.

Furthermore, the Secretary's interpretation would produce anomalous results. According to the Secretary's interpretation, the determination as to whether "the portion of the hospital" to which a resident is "assigned" is "subject to" PPS would depend upon the nature and purpose of the activity engaged in by the resident at that time. Thus, when a resident assigned to the orthopedic department spends time on direct patient care, the orthopedic department would be deemed "subject to" PPS and that time would be credited toward the FTE calculation. Conversely, when the resident spends time on other activities, the orthopedic department would be deemed not "subject to" PPS; and therefore, the time would not be credited toward the FTE calculation.

The crediting of time spent on the same types of activity, also would very from case to case. Thus, time spent by a resident on research would be credited toward the FTE calculation if it related to treatment of a particular patient; but, otherwise, time spent by the same resident on the same research would not be credited, even though, in both cases, the research was part of the hospital's approved teaching program.

It is not reasonable to interpret the Regulation in a way that attributes such chameleon-like features to a portion of a hospital

that cause its status to change from "subject to PPS" to not "subject to PPS" based solely on the nature or purpose of the activities engaged in by a resident at a particular time.

Finally, the Secretary's interpretation is not reasonable because it is incompatible with the meaning of a "full-time equivalent" as that term is commonly understood and as it is used in the Regulation. While the Regulation does not expressly define "full-time equivalent," subparagraph (iii) states that "[f]ull-time equivalent status is based on the total time necessary to fill a residency slot," 42 C.F.R. § 412.105(g)(1)(iii) (1996) (emphasis added).

Since research is required as part of an approved residency program, the "total time necessary to fill a residency slot" necessarily includes time spent on research. See Riverside 2003 WL 22658129 at *5 n.6 ("'total time necessary to fill a residency slot'... can only reasonably be read to include time spent by residents participating in required educational activities (which of course include, but certainly are not limited to, activities involving participation in the direct care and treatment of patients), because such activities would be 'necessary to fill a residency slot.'"). Under the Secretary's interpretation, a full time resident would not be considered an FTE because, not all of the resident's time would be spent on direct patient care.

Conclusion

For all of the foregoing reasons, RIH's motion for summary judgment is granted and the Secretary's motion for summary judgment is denied.³ Counsel for RIH are directed to confer with counsel for the Secretary and to submit a proposed form of judgment within 10 days from the date of this order.

IT IS SO ORDERED,

Ernest C. Torres

Sr. U.S. District Judge

Date: 8)9107

³Because this Court finds that the Secretary's interpretation of the Regulation is erroneous, there is no need to address RIH's argument that the Regulation itself is invalid.